

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

INVENTOR(S) : Rassoll Rashidi

TITLE : ELECTROPHYSIOLOGY/ABLATION CATHETER
AND REMOTE ACTUATOR THEREFOR

APPLICATION NO. : 09/232,866

FILED : January 15, 1999 #28

EXAMINER : Kennedy Schaetzle

ART UNIT : 3762

LAST OFFICE ACTION : June 16, 2003

ATTORNEY DOCKET NO. : STJD 2 00003-3-1

**COMMUNICATION AND TRANSMITTAL OF
RULE 37 C.F.R. § 1.192 APPELLANT'S BRIEF**

Mail Stop: AF

Commissioner for Patents
P. o. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed are three copies of a RULE 37 C.F.R. § 1.192 APPELLANT'S BRIEF and a check in the amount of \$ 330.00 in payment of fees upon filing the Brief. The Commissioner is authorized to charge any additional fees, or refund any overpayment to Deposit Account No. 06-0308.

Respectfully Submitted,

FAY, SHARPE, FAGAN,
MINNICH & McKEE, LLP

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TECHNOLOGY CENTER R3700

Timothy E. Nauman
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CERTIFICATE OF MAILING

I hereby certify that this COMMUNICATION AND TRANSMITTAL OF RULE 37 C.F.R. § 1.192 APPELLANT'S BRIEF and three (3) copies of the APPELLANT'S BRIEF are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313, Mail Stop: AF on February 17, 2004.

By: *Mary M. Schriener*
Mary M. Schriener

Date: *February 17, 2004*

PATENT

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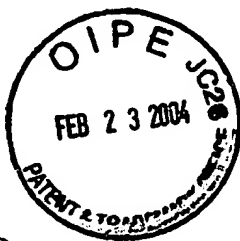
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TECHNOLOGY CENTER R3700

Dear Sir:

Appellant hereby submits a brief in triplicate as required under 37 C.F.R. §1.192 within two (2) months of the date of the Notice of Appeal, filed December 16, 2003. The Brief is accompanied by the fee of \$330.00 as required under Rule 17(c).

The Brief is organized under the appropriate headings and in the order as required by Rule 192(c).

CERTIFICATE OF MAILING

I hereby certify that this at this **BRIEF OF APPELLANT**, and all documents noted therein as being **enclosed** are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313, **Mail Stop AF** on February 17, 2004.

By: Mary M. Schirner
Mary M. Schirner

REAL PARTY OF INTEREST

The real party of interest is St. Jude Medical, Inc., which claims title via assignment from Cardiac Assist Devices, Inc. (to whom the application was originally assigned).

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to the appellant/assignee/legal representative that will directly affect, be directly affected, or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1, 6, and 41 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,462,527 to Stevens-Wright, et al. ("Stevens-Wright"). Claims 2-5, 42-45, 48, and 49 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Stevens-Wright.

Claims 7-11, 46, and 47 are objected to as being dependent from a rejected base claim but would be allowable if rewritten in independent form.

A complete listing of the claims currently pending is attached as **Appendix A**.

STATUS OF AMENDMENTS

A Response Under 37 CFR 1.116 was filed in response to the Office Action mailed June 16, 2003 finally rejecting claims 1-6, 41-45, 48, and 49. The claims were not amended in that Response. Rather, the Remarks requested reconsideration. Thus, the claims stand as identified in the 37 CFR 1.116 Response.

SUMMARY OF THE INVENTION

This application is directed to an electrophysiology/ablation catheter indicated generally by reference numeral 1. Spaced electrodes 3 are provided on a distal end and a subassembly, namely an actuator mechanism generally shown as

reference numeral **4** provides selective actuation of curvature of the distal end of the catheter. Each of the electrodes has an electrical conductor wire attached to it.

First and second tension/compression members **11, 12** extend along an inner guide tube **9**. The tension/compression members are secured at distal portions so that selective movement of actuator member **18** results in tension being applied "to one of the tension/compression members **11, 12**, and thereby effecting curvature formation at the distal portion **L** of the catheter" (page 27, lines 18-19).

"It will be understood that the inner guide tube **261** of FIGURE 29 or **9** of FIGURE 3A of the present invention is not loaded in compression when one of the members **266, 268** of FIGURE 29 or **11, 12** of FIGURE 3A is tensioned. Unlike the known catheters, the catheter of the present invention transmits the compression loading of the kinematic junction directly to the one of push/pull members **266, 278** of FIGURE 29 that is not being tensioned by the manual actuator and does not use a separate compression strut member to transmit compression load to the inner guide tube as in the case of known catheters. It will be understood that in the embodiment of FIGURES 28 and 29 the kinematic junction comprises of the weldment of collar **272** to **266', 268'**; and in the embodiment of FIGURE 3A the kinematic junction comprises the attachment of the pull/push or tension/compression members **11', 12'** to the distal end of portion **10** of inner guide tube **9**" (page 47, lines 5-16).

A spacer means **310**, which in one embodiment is a wave-shaped spring **310**, is disposed between flattened ends of tension/compression members **304, 306** as illustrated in FIGURE 32. One end is secured, for example by weldment as indicated at reference numeral **316** while the remainder of the flat spring is free-floating between the tension/compression members (page 48, lines 12-25).

ISSUES

The issue on appeal is whether Stevens-Wright discloses a pair of flexible tension/compression members so that upon movement of the actuator, the first tension/compression member of the pair undergoes tensioning and the second

tension/compression member of the pair undergoes compression to effect lateral displacement of a catheter distal end.

GROUPING OF CLAIMS

The claims stand or fall together relative to this issue.

ARGUMENT

Although the indication of allowable subject matter in objected to claims 7-11, 46, and 47 is appreciated, applicant still believes that the remaining claims, as represented by independent claims 1 and 41, already define over any fair teaching attributable to the prior art. Each of the independent claims requires a pair of "flexible tension/compression members". In an embodiment of applicant's invention, wires **11**, **12** serve as flexible tension/compression members as described in the Summary portion of this Brief. When the actuator is moved, longitudinal tensioning of the first tension/compression member occurs and simultaneous longitudinal compression of the second of the tension/compression members occurs to effect lateral displacement of the catheter of the distal end.

The Examiner has taken the position that Stevens-Wright discloses an electrophysiology catheter in which components 32a-32d meet these limitations regarding flexible tension/compression members. Particularly, the Examiner is of the view "that nothing in the '527 patent refers to one cable as being slack while the other is in tension. The showing in Fig. 13a of cable 32c could equally as well be a showing of a cable that is buckling (i.e., a cable that is under compressive force)." This interpretation and rejection is respectfully traversed. Cables 32a-32d are controlled by a thumb wheel actuator 92. Repeatedly, and throughout the written description of the Stevens-Wright patent, these cables are referred to as "pull" cables. Nowhere is there a teaching, nor even a remote suggestion, that the cables carry compressive forces in order to effect lateral displacement of the catheter distal end.

Moreover, it is respectfully asserted that the Stevens-Wright patent teaches away from such an arrangement. Column 6, lines 25-46 describe the selective

pulling of the pull cables to provide for essentially independent bending of proximal and distal portions of the catheter. "The bending of either section 15 or 16 is generally analogous to the bending of a cantilevered beam in the sense that one end of either section (i.e., the proximal end) is fixed while the entire section bends as tension is applied to a cable attached to the opposite end. To provide this result, it is necessary that the shaft 10 be stiffer than proximal section 15 and that the proximal section 15 be stiffer than the distal section 16." In other words, these catheter sections 10, 15, 16 in Stevens-Wright behave as a compressive member and thus a corresponding one of the pair of pull cables does not act as a compressive member. Rather, like the remaining art of record, known catheters transmit compression load through these other structures and not through one of the pair of tension/compression members as called for in both independent claims 1 and 41. Only applicant's disclosure teaches this arrangement. To modify Stevens-Wright or infer that one skilled in the art would conclude that the second member would carry compressive forces is directly contrary to the express teachings therein.


The illustration in Figures 13a-13f further support applicant's contention that Stevens-Wright illustrates a slack condition, i.e., it cannot carry compressive loads and thus is illustrated in such manner. It is respectfully asserted that the only teaching of transmitting the compressive loads through the second member of the pair of tension/compression members is through applicant's own disclosure. Without a teaching provided in the prior art, (including Falwell, et al. – U.S. Patent No. 5,944,690 or Stevens-Wright – U.S. Patent No. 5,383,852 (see paragraph 6 of June 16, 2003 Office Action)), the prior art still does not teach carrying compressive forces through a second of the tension/compression member pair. These alternative prior art teachings are allegedly not being relied upon for rejecting the claims "but rather as merely pointing to this reference as proof that the cables of the '527 patent are inherently tension/compression members." Either Stevens-Wright has an inherent teaching or it does not. It is respectfully submitted that reference to Falwell '690 or Stevens-Wright '852 is misplaced and is either a combination rejection or no reference is required at all to these documents. That is, Stevens-Wright '527 either stands on its own or it does not.

In light of the inadequacies of Stevens-Wright '527 as noted above, it is respectfully asserted that all claims patentable define thereover. Claims 1 and 41, and by definition the remaining dependent claims, define over Stevens-Wright, whether construed as an anticipatory prior art under 35 U.S.C. §102(b) or under a non-obviousness analysis under 35 U.S.C. §103.

Reversal of the Primary Examiner's rejections is respectfully requested.

Respectfully submitted,

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APPENDIX A

Complete listing of the pending claims:

1. (Previously Amended) An electrophysiology/ablation catheter comprising:
 - a) an elongated flexible hollow tubular casing having a proximal end and a distal end and a plurality of spaced electrodes disposed at the distal end thereof;
 - b) a pair of flexible tension/compression members disposed in side by side relationship and extending in the hollow of said casing from a point of attachment adjacent said distal end to said proximal end of said tubular casing;
 - c) an electrical lead connected to each of said electrodes and extending through the hollow of said tubular casing to the proximal end thereof, said lead adapted for external connections thereto;
 - d) spacer means disposed between said pair of flexible tension/compression members at said distal end for maintaining lateral spacing between said members, said spacer means being flexible; and
 - e) a handle including an actuator moveable in opposite directions and operative for effecting upon movement in one direction longitudinal tensioning of a first of said tension/compression members and simultaneous longitudinal compressing of the second of said tension/compression members with respect to said casing which effects lateral displacement of said distal end of said casing in one direction and upon movement in a direction opposite said one direction operative for effecting longitudinal tensioning of the said second of tension/compression members with respect to said casing which effects lateral displacement of said distal end of said casing in a direction opposite said one direction.
2. (Previously Amended) The catheter defined in Claim 1, wherein said pair of tension/compression members each have a portion thereof adjacent said distal end with a flattened transverse section.
3. (Previously Amended) The catheter defined in Claim 1, wherein said spacer means comprises a spring member.

4. (Original) The catheter defined in Claim 1, wherein the spacer means comprises a wave shaped spring member.

5. (Previously Amended) The catheter defined in Claim 1, wherein each of said tension/compression members has substantially rectangular transverse section in the region adjacent the distal end with the balance thereof having a generally circular cross-section.

6. (Original) The catheter defined in Claim 1, further comprising an elongated flexible tubular guide member disposed in said casing, said guide member having a pair of spaced parallel lumens formed therein with one of said pair of tension/compression members disposed in each lumen.

7. (Previously Amended) The catheter defined in Claim 2, further comprising a sleeve received over said flattened portion of said tension/compression members and spaced a preselected distance from said distal end, said tension/compression members secured therein and forming a kinematic junction at said sleeve, wherein the portion of said tubular casing distal said sleeve remains substantially un-deformed upon simultaneous tensioning and compressing of said tension /compression members.

8. (Original) The catheter as defined in Claim 7, wherein said spacer means has an end thereof secured in said sleeve with the other end of said spacer floating in the space between said tension/compression members.

9. (Original) The catheter as defined in Claim 1, further comprising an elongated flexible tubular guide member disposed in said casing with said tension/compression members received therethrough; and,

a rigid collar attached to the distal end of said guide member and extending over a portion of said tension/compression members having said spacer means therebetween.

10. (Original) The catheter as defined in Claim 9, wherein said rigid collar has a flatted cross-section on one end and a generally circular cross-section on an opposite said one end.

11. (Original) The catheter as defined in Claim 1, further comprising an annular reference electrode disposed on said tubular casing at a station therealong remote from said plurality of spaced electrodes, wherein said reference electrode is located such that it remains exterior to the heart cavity upon insertion of the said plurality of spaced electrodes into a heart cavity.

41. (Previously Added) An electrophysiology/ablation catheter comprising:

- a) an elongated flexible hollow casing having a proximal end and a distal end and a plurality of spaced electrodes disposed at the distal end thereof;
- b) first and second flexible tension/compression members disposed and extending in the hollow of said casing from a point of attachment adjacent said distal end to said proximal end of said casing;
- c) an electrical lead connected to each of said electrodes and extending through the hollow of said casing to the proximal end thereof, said lead adapted for external connections thereto;
- d) a flexible spacer disposed between the first and second flexible tension/compression members at said distal end for maintaining lateral spacing between said members; and
- e) a handle including an actuator moveable in opposite directions and operative for effecting upon movement longitudinal tensioning of the first tension/compression member and simultaneous longitudinal compressing of the second tension/compression member with respect to the casing which effects lateral displacement of the distal end of the casing in a desired direction.

42. (Previously Added) The catheter defined in Claim 41, wherein the first and second tension/compression members each have a portion thereof adjacent the distal end with a flattened transverse section.

43. (Previously Added) The catheter defined in Claim 41, wherein the flexible spacer is a spring.

44. (Previously Added) The catheter defined in Claim 41, wherein the first and second flexible tension/compression members each have a substantially rectangular transverse section adjacent the distal end.

45. (Previously Added) The catheter defined in Claim 44 wherein the first and second flexible tension/compression members are secured to one another and form a kinematic junction adjacent the substantially rectangular transverse sections.

46. (Previously Added) The catheter defined in Claim 45 wherein the flexible spacer has a first end secured to the first and second flexible tension/compression members at the kinematic junction.

47. (Previously Added) The catheter defined in Claim 46 wherein the flexible spacer has a second end floating in space between the first and second flexible tension/compression members.

48. (Previously Added) The catheter defined in Claim 41 wherein the first and second flexible tension/compression members have flattened transverse sections adjacent the distal end, and the catheter further comprises a sleeve received over the flattened sections.

49. (Previously Added) The catheter defined in Claim 48 wherein the first and second flexible tension/compression members are secured to one another and form a kinematic junction adjacent the flattened sections.